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LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			SHOME, ARUNDIPTA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,247	Applicant(s) CHALVIGNAC, PHILIPPE
	Examiner ARUNDIPTA SHOME	Art Unit 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 May 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 September 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claims 1-16 are pending. This Action is in response to the preliminary amendment filed on 5-15-2006. Claims 1-16 have been amended as directed by the preliminary amendment.

Drawings

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, the following limitations render the claim unclear and indefinite:

There is a lack of antecedent basis for "the expiratory gas source" on line 20.

For "the valve being controlled by means which are distinct from the respiratory gas source", it is unclear what structural element controls the valve on lines 18-19.

Also, it is unclear if the “automatic control unit” recited on line 30 is distinct from the control means recited on line 7. Applicant’s Figure 2 shows the control means as a control circuit rather than an individual structural element, is the control means or automatic control unit referring to a specific element?

On lines 37-39, it is recited that the automatic control unit is “associated to a programme allowing a selection..” but it is unclear what structural element permits this selection.

On lines 39-40 it is stated that “association of a direct closed regulation loop” exists but it is unclear what structural element comprises this regulation loop.

On lines 42-43, it is not clear what structural element provides control of the barometric and volumetric modes.

Regarding Claim 2, the claim is confusing because it appears contradictory. It is recited that “the valve is operable to generate a leak rate to compensate leaks so that no leak connection is associated with the valve.” Does the valve generate leaks or does it not?

Regarding Claim 6, a “processor” is recited on line 4, but a “comparison means,” a “processing means,” an “automatic control unit,” and a “control means” are all previously recited. It is unclear what the structural differences between each claimed item are, all items appear to processors of some sort.

Regarding Claim 7, it is unclear what structure is defined by the “all or nothing operation” on line 18. Examiner suggests claiming the structure of the valve more specifically rather than the function.

Regarding Claim 8, it is unclear how the recess can align with itself - the recess has a first and second part, yet the claim recites the recess aligning with the first and second parts.

Regarding Claims 12 and 14, the same issues noted with respect to claim 1 apply to these claims as well.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 10, 12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chalvignac (US PGPub 2002/0014239 A1) in view of Ernst (US Patent 3,961,627).

Regarding Claim 1, Chalvignac discloses a breathing assistance apparatus capable of operating in alternating inhalation and exhalation phases (para. 0015, lines 1-5). A pressurized gas source (12, see para. 0060 lines 1-5) is disclosed. Chalvignac also discloses control means 34 capable of transmitting a reference value of a gas related parameter to the gas source (para. 0024, lines 5-9). An inhalation duct 14 and an expiration duct 26 are shown in Figure 1.

An inhalation valve 16 is on the inhalation duct and permits proportional operation (para. 0061, lines 1-10).

A pressure sensor and a flow sensor 22 are on the inhalation duct (para. 0062, line 5). Chalvignac does not disclose a selection means for selecting a parameter of flow or pressure to define the gas related parameter. Ernst teaches a selection means (comparator 7) capable of selecting a parameter of flow or pressure to define a gas related parameter (see col. 4, lines 5-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made

to modify the system of Chalvignac to include a selection means as taught by Ernst in order to permit switching between volume and pressure based regulation (see Ernst col. 4, lines 36-44).

Chalvignac does not disclose an automatic control unit separate from the control means noted above. Ernst teaches an automatic control unit 8 for controlling the selection means. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Chalvignac to include an automatic control unit as taught by Ernst so that the selection means of Ernst can function properly as shown in Fig 1 of Ernst. This combination of Chalvignac and Ernst forms a direct closed regulation circuit for selecting a reference value parameter (see Ernst col. 4, lines 20-22).

The combination of Chalvignac and Ernst noted above has a program permitting selection to be made in real time from a pressure signal or flow signal, because Ernst teaches this function (col. 4, lines 36-44) and the electronic circuitry of Ernst inherently operates in real time and inherently has programming permitting this.

The combination of Chalvignac and Ernst noted above includes permits real time control of barometric and volumetric operating modes of the breathing assistance apparatus, between or during inhalation and expiratory phases (see col. 4, lines 36-44, Ernst teaches pressure and volume based operation in real time).

Regarding Claim 2, the inhalation valve is operable to generate leaks (para. 0061, line 6).

Regarding Claim 3, the gas source is a centrifugal fan turbine with an axial air intake and peripheral output (para. 0060, lines 1-5). Chalvignac does not disclose the inertia value/moment of inertia of the fan is $150 \text{ g}*\text{cm}^2$. However, it would have been obvious at the time the invention was made to modify the inertia value/moment of inertia of the fan to be $150 \text{ g}*\text{cm}^2$ since it has

been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding Claim 10, a micro turbine (the fan) is operable to control the expiratory valve so that positive expiratory pressure is controlled (para. 0043, lines 1-4, para. 0071, lines 1-5).

Regarding Claim 12, the structural elements recited are noted above with respect to claim 1. Chalvignac also discloses operating a microturbine (para. 0043, lines 1-4) and closing the expiratory valve based on the micro turbine to regulate a positive expiratory pressure during the expiratory phase (para. 0071, lines 1-5).

Regarding Claim 14, the structural elements recited are noted above with respect to claim 1. Chalvignac also discloses selecting the volumetric mode (para. 0024, lines 1-9), controlling the gas source on the basis of a measured pressure parameter in the inhalation duct (para. 0018, lines 1-5), and wherein control of the volume of gas delivered is obtained by control of the gas source (para. 0024, lines 1-9).

Regarding Claim 15, no pressure difference exists between the upstream part and the downstream part of the ventilator shown in Figure 1 when the inhalation valve opens. Flow is also permitted through bypass pip 18, which eliminates pressure differences.

Regarding Claim 16, control of the volume of gas delivered is obtained by control of the rotation speed of a rotor of the gas source (para. 0027, lines 1-3).

6. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chalvignac (US PGPub 2002/0014239 A1) in view of Ernst (US Patent 3,961,627) as applied to claim 1 above, further in view of Whitwam (US Patent 5,307,795).

Regarding Claim 4, Chalvignac does not disclose a second flow sensor on the expiratory duct. Whitwam teaches a flow sensor 15 on an expiratory duct (col. 2, line 54, see Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Chalvignac to include a second flow sensor as taught by Whitwam so that the total expired volume from the patient can be measured.

Chalvignac does not disclose a comparison means for the flow rate sensors to compare the respective flow rates in the inhalation and exhalation ducts. Whitwam teaches a comparison means 20 (col. 3, lines 5-15) for comparing the respective flow rates in the inhalation and exhalation ducts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Chalvignac to include a comparison means as taught by Whitwam so that the expired tidal volume can be measured (col. 3, line 13).

Regarding Claim 5, Whitman also teaches processing means 23 (col. 3, line 15) operable to filter a difference between the respective flow rates in real time, The processing means is associated with the comparison means (Fig. 1).

Regarding Claim 6, the combination of Chalvignac and Whitwam will have the processing means connected to the automatic control unit of Chalvignac.

The modified Chalvignac system does not disclose a memory connected the processing means. Whitwam discloses a memory 24 connected to a processing means. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Chalvignac to include a memory connected to the processing means as taught by Whitwam so that flow rate measurements can be stored.

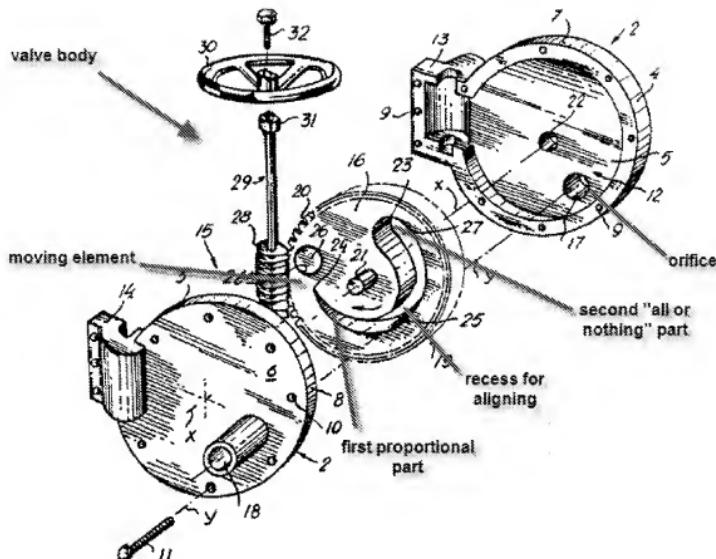
The modified Chalvignac system does not appear to disclose a separate processor.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a processor well known in the art to the modified system of Chalvignac in order to control the flow sensors noted above with respect to claim 5.

The addition of Whitwam's sensors and comparison means as noted above includes circuitry programmed to trigger a new inhalation phase when the filtered flow rate difference is higher than a pre-determined threshold (col. 1, lines 49-62).

7. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chalvignac (US PGPub 2002/0014239 A1) in view of Ernst (US Patent 3,961,627) as applied to claim 1 above, further in view of Torres (US Patent 5,308,040).

Regarding Claim 7, Chalvignac's inhalation valve 16 inherently has an orifice connected to the inhalation duct. This valve is a balloon valve, so it also appears to be operable to block the orifice in a closed position and partially free the orifice in an open position. However, Chalvignac does not disclose the valve comprising a recess for aligning with the orifice with the recess having a first part with a proportional operation and a second part with an all or nothing operation. Torres teaches a valve with a recess for aligning with the orifice with the recess having a first part with a proportional operation and a second part with an all or nothing operation, as shown below. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Chalvignac's inhalation valve with the valve as taught by Torres because both valve structures were well known in the art and substituting one valve for another would work equally well.



Regarding Claim 8, Torres's valve has the recess is shaped so that when the moving element moves from the closed position to the open position, the first part is aligned with the orifice, and the second part is aligned with the orifice if the movement continues (clockwise motion in the figure above).

Regarding Claim 9, the first part of the recess show above is triangular at the tip. The second part of the recess is not rectangular. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape to be rectangular.

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because a mere change in shape is generally considered to be obvious to one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

The base of the triangle of the first part shown above would be parallel to one of the sides of the rectangular end of the recess shown above.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chalvignac (US PGPub 2002/0014239 A1) in view of Ernst (US Patent 3,961,627) as applied to claim 10 above, further in view of DeVries (US Patent 6,102,038).

Regarding Claim 11, Chalvignac does not disclose that the micro turbine is directly connected to the expiratory valve with no element in between. DeVries teaches a balloon valve 32 (Fig. 1) directly connected to an air source 56 with no element in between. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Chalvignac to have the fan directly connected to the inhalation valve as taught by DeVries so that the valve can be easily controlled by slowing or accelerating the fan to deflate or inflate the valve.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chalvignac (US PGPub 2002/0014239 A1) in view of Ernst (US Patent 3,961,627) as applied to claim 12 above, further in view of Tobia (US Patent 5,735,267).

Regarding Claim 13, Chalvignac discloses the micro turbine operating constantly (para. 0060, line 4).

Chalvignac does not disclose the expiratory valve controlled by selective connection of a pneumatic control line of the expiratory valve with the micro turbine. Tobia teaches an exhalation valve 26 that is a balloon valve (col. 4, line 36) that is controlled by selective control

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of a pneumatic control line 18 via flow control solenoid valve 16 (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Chalvignac to include a solenoid controlling flow to the expiratory valve as taught by Tobia so that a controller can precisely control the inflation and deflation of the balloon valve.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Du (US Patent 6,622,726) discloses a ventilator with pressure and flow regulation.

Psaros (US Patent 6,095,139) discloses a ventilator with adjustable pressure or flow rates.

Eber (US Patent 5,417,083) discloses a proportional valve.

Gropper (US Patent 5,540,220) discloses a pressure or volume regulated ventilator.

Jafari (US Patent 6,626,175) discloses a ventilator triggering mechanism.

Froelich (US Patent 5,503,146) discloses a ventilator with pressure and flow feedback for a gas source.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is (571)270-5539. The examiner can normally be reached on Monday through Friday 8:30am to 6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Arun Shome/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771